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Serial No. 09/745,960
Response to Official Action

In the Drawings

There are no amendments to the drawings.

Remarks

Applicant has cancelled Claims 1 – 24 and added new Claims 25 – 45. Applicant respectfully submits that no new matter was added by the amendment, as all of the amended matter was either previously illustrated or described in the drawings, written specification and/or claims of the present application. Entry of the amendment and favorable consideration thereof is earnestly requested.

The Examiner has rejected Claims 1 – 3, 5, 6, 8 and 20 – 22 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,241,771 to Gresser et al. (“the ‘771 patent”) in view of U.S. Patent No. 5,941,883 to Jammet et al. (“the ‘883 patent”). The Examiner has further rejected Claims 14 and 24 under 35 U.S.C. § 103(a) as unpatentable over the ‘771 patent in view of the ‘883 patent and further in view of PCT Patent Publication No. WO 99/44533 to Stone et al. (“the ‘533 application”). These rejections are respectfully traversed.

35 U.S.C. § 103(a) Rejections

All new claims require among other elements, said screw body contacting the transplant positioned between said screw body and a side of the opening in the bone to anchor said transplant to said bone. Applicant submits that neither the ‘771 patent nor the ‘883 patent teach this limitation.

For example, the '771 patent teaches "an interbody spinal fusion device (IFD) comprising a resorbable spinal wedge for vertebral spacing as an adjunct to spinal fusion." (col. 3, lines 63 – 66). The spinal fusion device taught in the '771 patent not only facilitate spinal fusion, but is provided as a structural member for the vertebra being provided with "serrated or threaded faces to stabilize and align vertebral bodies." (col. 4, lines 4 – 5). To that end, the spinal fusion device is provided to withstand large forces such that the "[s]trength requirements depend on the location of the disc to be replaced" where, for example, it has been "determined that the force on the lumbar disc in a sitting position is more than three times the weight of the trunk." (col. 6, lines 9 – 10 & 14 – 16). Therefore, the screw type embodiment of the spinal fusion device taught in Figures 2A – 2C is positioned to structurally support the members surrounding the device. The device is positioned between the members tightly and with enough force to stabilize and align the members. However, to position a transplant between the device and the member it is supporting would result in damage or destruction of the transplant.

It is well settled that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). In this case any modification to provide for a reduction in the force applied between the spinal fusion device that the member(s) it is supporting to located an implant therebetween, would result in the device being unusable as a spinal fusion device and therefore cannot be obvious.

In addition, the large protrusions, threading and sharp edges of the device as taught in Figures 2A – 2C would cause damage to any transplant positioned between the spinal fusion device and the member it is supporting. Alternatively, as seen in Figures 8 and 9 of the present application, the no large protrusions or deep channels are provided that will damage the transplant in contact with the screw body. Removal of these features would result in a device that would be less efficient as a spinal fusion device and therefore cannot be obvious. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (See, Col. 1, line 60 – Col. 2, line 7; & Col. 4, lines 35 – 42).

In fact, it is unclear as to whether the device taught in the '771 patent could even anchor a transplant considering the very large gaps between the outer threading, which would present a very poor anchoring surface as the transplant would have absolutely no support from the screw device for the area between the gaps in the threads.

Accordingly, Applicant respectfully submits that the '771 patent fails to teach, disclose or suggest a screw body contacting the transplant positioned between the screw body and a side of the opening in the bone to anchor said transplant to said bone. In addition, Applicant respectfully submits that in order to use the spinal fusion device to anchor a transplant, significant modifications would have to be made to the device so that the device could serve to anchor and not damage the transplant. Accordingly, applicant respectfully submits that the present claims cannot be obvious in view of the '771 patent.

Applicant further respectfully submits that the '883 patent also fails to teach a screw body contacting the transplant positioned between the screw body and a side of the opening in the bone to anchor said transplant to said bone as required by all the claims. It is well settled that the mere fact that a reference can be modified does not render the resultant modification obvious unless the prior art also suggests the desirability of the modification. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). In this case, the '883 patent teaches away from this limitation. As can be seen from FIG. 4, the screw of the '883 patent does not contact the transplant positioned between the screw and the opening. Rather, the '883 patent teaches positioning the screw in the opening and then attaching the transplant to the screw as a suture anchor arrangement. (See, Figures 7A & 7B). There is no motivation to modify this reference to discard its primary teachings in view of the present application. Accordingly, the '883 patent teaches away from a screw body contacting the transplant positioned between the screw body and a side of the opening in the bone to anchor said transplant to said bone as required by all the claims.

Applicant further respectfully submits that there is no motivation to combine the spinal fusion device taught in the '771 patent with the suture anchor taught in the '883 patent as they relate to none analogous prior art. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Nowhere does the '771 patent teach, disclose or suggest that the spinal fusion device may be used to anchor transplants. In fact, if one were to combine the references as suggested, would not arrive at the present claim in-

vention, rather, one would have a spinal fusion device/suture anchor arrangement. Therefore, no combination of the cited prior art can render the pending claims obvious because none of the cited references teaches a screw body contacting the transplant positioned between the screw body and a side of the opening in the bone to anchor said transplant to said bone as required by all the claims.

Applicant further respectfully submits that none of the cited references teach, disclose or suggest, a tool that has a protrusion corresponding to a recess in the screw head for centering said tool with respect to said screw body during insertion as required by Claim 25.

The Examiner has cited the '883 patent as reciting a drive tool. However, the tool taught in the '883 patent does not have a protrusion corresponding to a recess in the screw head for centering said tool as required by Claim 26. (*See*, Figures 1 & 8). Applicant further respectfully submits that there is absolutely no motivation to add such a protrusion because the tool taught in the '883 patent does not need centering as it is provided with two opposing screwing lugs 150, which provides centering for the tool. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990) (The mere fact that a reference can be modified does not render the resultant modification obvious unless the prior art also suggests the desirability of the modification.)

Accordingly, because none of the cited prior art teaches, discloses or suggests, a tool that has a protrusion corresponding to a recess in the screw head for centering said

tool with respect to said screw body during insertion as required by Claim 26, no combination thereof can render Claim 25 obvious.

Applicant further respectfully submits that none of the cited references teach, disclose or suggest, a screw body including at least three axially extending grooves, or a tool including at least three drive elements for insertion into said at least three axially extending grooves as required by Claim 36.

Rather, the '771 patent teaches provision of four recesses "to facilitate ingrowth of tissue that would aid in anchoring the device in place." (col. 4, line 41 – 42). To insert spinal fusion device, "a cylindrical axially extending hole 23 and slots 24 . . . facilitate screwing the device into the spine of the patient." (col. 4, lines 38 – 40). Applicant respectfully submits that there is no motivation to disregard this teaching of the '771 patent.

So to, the '883 patent also fails to teach, disclose or suggest this limitation. For example, the '883 patent teaches use of two longitudinal grooves that may receive two screwing lugs. Therefore, even if one were to combine the '771 patent with the '883 patent, one would still have to further modify the combination to reach the pending claims. Applicant respectfully submits that there is no motivation to make this further modification except in view of the present application. *W. L. Gore and Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13, (Fed. Cir. 1983), *cert. de-*

nied, 469 U.S. 851 (1984) (The use of hindsight knowledge to support an obviousness rejection under 35 U.S.C. § 103 is impermissible.)

Applicant further respectfully submits that the '533 application fails to teach the novel combination of limitations recited in the pending claims.

It is respectfully submitted that claims 25 – 45, all of the claims remaining in the application, are in order for allowance and early notice to that effect is respectfully requested.

Respectfully submitted,



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